



07-02-04

JPW/615

Docket 17359-CON2-CIP-CIP (BOT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: STEPHEN DONOVAN	)	Examiner:
	)	
Serial Number: 10/752,871	)	
	)	Art Unit: 1615
Filed: January 16, 2004	)	
	)	Confirmation No.: 4854
For: INTRAVITREAL BOTULINUM	)	
<u>TOXIN IMPLANT</u>	)	Irvine, California

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:


Applicant's provide with regard to the patent application entitled INTRAVITREAL BOTULINUM TOXIN IMPLANT, filed herewith one copy of documents of which they are aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of documents submitted is set forth on the attached Information Disclosure Citation (Form PTO-1449).

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: June 30, 2004

  
Stephen Donovan  
Registration Number 33,433

Please direct all inquiries and correspondence to:

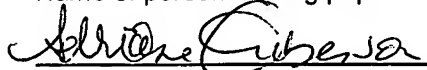
Stephen Donovan  
Allergan, Inc.  
2525 Dupont Drive, T2-7H  
Irvine, California 92623-9534  
Tel: 714.246.4026  
Fax: 714.246-4249

**CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10**

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date June \_\_, 2004, in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV193717108US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Adriane Giberson

Name of person mailing paper



Signature of person mailing paper

Date: June 30, 2004



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<b>APPLICANT:</b> Stephen Donovan	<b>TITLE:</b> INTRAVITREAL BOTULINUM TOXIN IMPLANT
<b>FILING DATE:</b> January 6, 2004	<b>GROUP:</b> 1615

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	2003-0095995					
	AB	3,523,906					
	AC	3,691,090					
	AD	3,737,337					
	AE	3,773,919					
	AF	4,389,330					
	AG	4,767,628					
	AH	5,019,400					
	AI	5,437,291					
	AJ	5,501,856					
	AK	5,667,808					
	AL	5,670,484					
	AM	5,714,468					
	AN	5,766,605					
	AO	5,902,565					
	AP	5,980,945					
	AQ	5,980,948					
	AR	6,007,843					
	AS	6,011,011					
	AT	6,022,554					
	AU	6,063,768					
	AV	6,113,915					
	AW	6,139,845					
	AX	6,143,306					
	AY	6,265,379					
	AZ	6,299,893					
	AAA	6,306,403					
	ABB	6,306,423B1					
	ACC	6,312,708					
	ADD	6,328,977					

EXAMINER \_\_\_\_\_ DATE CONSIDERED \_\_\_\_\_

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	AEE	6,358,513					
	AFF	6,365,164B1					
	AGG	6,383,509B1					
	AHH	6,395,277					
	All	6,423,319					
	AJJ	6,458,365					
	AKK	6,464,986					
	ALL	6,699,493					
	AMM	6,726,918					

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA	EP 654,256					
	BD						

**OTHER ART**

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	am Ende, M.T. et al., <i>Factors influencing drug and protein transport and release from ionic hydrogels</i> , Reactive Polymers, 25 (1995);127-137
	CB	Aoki K.R., Cui M, <i>Mechanisms of the Antinociceptive Effect of Subcutaneous BOTOX®: Inhibition of Peripheral and Central Nociceptive Processing</i> , Cephalalgia 23(7);649:2003
	CC	Aoki K.R., <i>Pharmacology and immunology of botulinum toxin serotypes</i> , J Neurol 248(suppl 1);l/3 -l/10:2001
	CD	Argoff, <i>A Focused Review on the Use of Botulinum Toxins for Neuropathic Pain</i> , Clin J Pain (2002) 18(6 Suppl);S177-S181
	CE	Bell, C. et al., <i>Poly(methacrylic Acid-g-Ethylene Glycol) Hydrogels as pH Responsive Biomedical Materials</i> , Mater Res Soc Symp Proc (1994), 331;199-204
	CF	Bigalke H., et al., <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> , Brain Research 360 (1985);318-324

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	CG	Bigalke H., et al., <i>Tetanus Toxin and Botulinum A Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations From Rat Brain and Spinal Cord</i> , Naunyn-Schmiedeberg's Arch Pharmacol 316 (1981);244-251
	CH	Binz T. et al., <i>The Complete Sequence of Botulinum Neurotoxin Type A and Comparison with Other Clostridial Neurotoxins</i> , J Biological Chemistry 265(16);9153-9158 (1990)
	CI	Brazel C. et al., <i>Temperature- and pH- Sensitive Hydrogels for Controlled Release of Antithrombotic Agents</i> , Mater Res Soc Symp Proc (1994), 331;211-216
	CJ	Bushara K., <i>Botulinum toxin and rhinorrhea</i> , Otolaryngology - Head Neck Surg 1996;114(3):507
	CK	Cardamone M., et al., <i>In Vitro Testing of a Pulsatile Delivery System and its In Vivo Application for Immunization Against Tetanus Toxoid</i> , J Controlled Release 47;205-219:1997
	CL	Cleland J.L., et al, <i>Development of a Single-Shot Subunit Vaccine for HIV-1: Part 4. Optimizing Microencapsulation and Pulsatile Release of MN rpg120 from Biodegradable Microspheres</i> , J Cont Rel 47;135-150:1997
	CM	Cleland, J. et al., <i>Development of a Single-shot Subunit Vaccine for HIV-1. 5. Programmable in Vivo Autoboot and Long Lasting Neutralizing Response</i> , J Pharm Sci (1998) 87:1; 1489-95
	CN	Cleland, Jeffrey L., <i>Solvent Evaporation Processes for the Production of Controlld Release Biodegradable Microsphere Formulations for Therapeutics and Vaccines</i> , Biotechnol Prog (1998), 14(1):102-7
	CO	Coffield J., et al., <i>Site and Action of Botulinum Neurotoxin</i> , Therapy With Botulinum Toxin, Ed. Jankovic J. et al., Publ. Marcel Dekker, Inc., (1994), page 5
	CP	Cui M, Aoki KR, <i>Botulinum toxin type A (BTX-A) reduces inflammatory pain in the rat formalin model</i> , Cephalalgia 20(4);414:2000
	CQ	Doelker E., <i>Cellulose Derivatives</i> , Adv Polym Sci 107; 199-265:1993
	CR	Dong, Liang-Chang et al., <i>A novel approach for preparation of pH-sensitive hydrogels for enteric drug delivery</i> , J. Contr Rel 15 (1991);141-152
	CS	Durham P., et al., <i>Mechanism of botulinum toxin type-A Inhibition of Calcitonin Gene-Related Peptide Secretion from Trigeminal Nerve Cells</i> , Cephalalgia (2003) 23(7);690
	CT	Garry, M. et al., <i>Evaluation of the efficacy of bioerodible bupivacaine polymer system on antinociception and inflammatory mediator release</i> , Pain 82 (1999);49-55

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	CU	Gonelle-Gispert et al., <i>SNAP-25a and -25b isoforms are both expressed in insulin-secreting cells and can function in insulin secretion</i> , Biochem J. 339 (1999) (pt 1):159-165
	CV	Habermann E. et al., <i>Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release From Cultured Mouse Brain</i> , J Neurochem (1988), 51(2):522-527
	CW	Habermann E., <i>Inhibition by Tetanus and Botulinum A Toxin of the release of [<sup>3</sup>H]Noradrenaline and [<sup>3</sup>H]GABA From Rat Brain Homogenate</i> , Experientia 44 (1988);224-226
	CX	Habermann, E., <i>I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord</i> , Naunyn-Schmiedeberg's Arch. Pharmacol. 1974; 281, 47-56
	CY	Hanes, J. et al., <i>New Advances in Microsphere-Based Single-Dose Vaccines</i> , Adv Drug Del Rev 28 (1997);97-119
	CZ	Heller, <i>Biodegradable Polymers in Controlled Drug Delivery</i> , CRC Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 1, Issue 1, Boca Raton, FL (1987); 39-90
	CAA	Johansen P. et al., <i>Improving Stability and Release Kinetics of Microencapsulated Tetanus Toxoid by Co-Encapsulation of Additives</i> , Pharm Res 15:7(1998);1103-1110
	CBB	Kissel et al., <i>Microencapsulation of Antigens Using Biodegradable Polymers: Facts and Fantasies</i> , Behring Inst. Mitt., 98 (1997);172-183
	CCC	Kost, J. et al., <i>Magnetically enhanced insulin release in diabetic rats</i> , J. Biomed Mater Res (1987), 21;1367-1373
	CDD	Langer, R. et al., <i>Polymers for Sustained Release of Proteins and Other Macromolecules</i> , Nature 263 (1976); 797-800
	CEE	Langer, R., <i>New Methods of Drug Delivery</i> , Science 249 (1990);1527-1533
	CFF	Lewis D. H., <i>Controlled Release of Bioagents from Lactide/Glycolide Polymers</i> , Biodegradable Polymers as Drug-Delivery Systems, Ed. Chasin M., et al., Marcel Dekker, New York (1990), pages 1-41
	CGG	Mallapragada S.K. et al., <i>Drug Delivery Systems</i> , chapter 27, Ed. Von Recum, A. F. <i>Handbook of Biomaterials Evaluation</i> , second edition, Publ. Taylor & Francis (1999), 431-433
	CHH	Marchese Ragona, R. et al., <i>Management of Parotid Sialoceles With Botulinum Toxin</i> , The Laryngoscope 109 (August 1999):1344-1346

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	CII	Men Y. et al., <i>A Single Administration of Tetanus Toxoid in Biodegradable Microspheres Elicits T Cell and Antibody Responses Similar or Superior to Those Obtained with Aluminum Hydroxide</i> , Vaccine (1995) 13, 683-689
	CJJ	Movement Disorders, Vol. 10, No. 3 (1995), pg. 376
	CKK	Moyer E. et al., <i>Botulinum Toxin Type B: Experimental and Clinical Experience of "Therapy With Botulinum Toxin"</i> , edited by Jankovic, J. et al. (1994), Marcel Dekker, Inc., Chapter 6, pages 71-85
	CLL	Naumann, M. et al., <i>Botulinum toxin type A in the treatment of focal, axillary and palmar hyperhidrosis and other hyperhidrotic conditions</i> , European J. Neurology (1999), 6 (Supp 4): S111-S115
	CMM	Pearce, L.B., <i>Pharmacologic Characterization of Botulinum Toxin For Basic Science and Medicine</i> , Toxicon 1997; 35(9);1373-1412 at 1393
	CNN	Powell, E. et al., <i>Controlled Release of Nerve Growth Factor from a Polymeric Implant</i> , Brain Res 1990;515(1-2):309-11
	COO	Rao, Jyoti et al., <i>Implantable Controlled Delivery Systems for Proteins Based on Collagen - pHEMA Hydrogels</i> , Biomaterials 1994;15(5):383-9
	CPP	Sanchez-Prieto, J. et al., <i>Botulinum Toxin A Blocks Glutamate Exocytosis From Guinea Pig Cerebral Cortical Synaptosomes</i> , Eur J. Biochem (1987) 165(3);675-681
	CQQ	Schantz, E.J., et al, <i>Properties and use of Botulinum toxin and Other Microbial Neurotoxins in Medicine</i> , Microbiological Reviews (1992), 56(1);80-99
	CRR	Schwendeman, S. et al., <i>Peptide, Protein, and Vaccine Delivery from Implantable Polymeric Systems-Progress and Challenges</i> , from Controlled Drug Delivery Challenges and Strategies, American Chemical Society (1997), Ed. Park K., chapter 12 (pages 229-267)
	CSS	Silberstein S. et al., <i>Botulinum toxin type A: Myths, facts, and current research</i> , Headache 2003 Jul;43 Suppl 1 1(Suppl 1);S1
	CTT	Singh, <i>Critical Aspects of Bacterial Protein Toxins</i> , pages 63-84 (chapter 4) of Natural Toxins II, edited by B.R. Singh et al., Plenum Press, New York (1976)
	CUU	Sinha V. et al., <i>Bioabsorbable Polymers for Implantable Therapeutic Systems</i> , Drug Development and Industrial Pharmacy 24(12);1129-1138 (1998)
	CVV	Sloop, R. et al., <i>Reconstituted botulinum toxin type A does not lose potency in humans if it is refrozen or refrigerated before 2 weeks before use</i> , Neurology 48 (January 1997):249-53:1997

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	CWW	Tobio M., et al., <i>A Novel System Based on a Poloxamer/PLGA Blend as a Tetanus Toxoid Delivery Vehicle</i> , Pharm Res (1999) 16(5);682-688
	CXX	Tracy et al., <i>Factors affecting the degradation rate of poly(lactide-co-glycolide) microspheres in vivo and in vitro</i> , Biomaterials 20 (1999):1057-1062
	CYY	USP 24; NF 19 (2000), pp. 1941-1951
	CZZ	Veronese, F.M. et al., <i>Polyorganophosphazene microspheres for drug release: polymer synthesis, microsphere preparation, in vitro and in vivo naproxen release</i> , Journal of Controlled Release 52 (1998);227-237
	CAAA	Weigand et al, <i>I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats after Intramuscular Injection</i> , Naunyn-Schmiedeberg's Arch. Pharmacol. 1976; 292, 161-165

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